



MEDICAL SYSTEMS INC.

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Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Kane,
Room 1061,
Rockville, MD, 20852

Attention : Mr. Philip Chao

5th October 1999

Dear Mr. Chao,

I am writing in regards to the proposed FDA regulations for Foreign Establishment Registration and Listing.

Techlem Medical is a private Canadian company which manufactures sterilisation and medical packaging for hospitals, doctors' and dentists' offices as well as for medical device companies. Our revenue is about \$2m per annum of which approx 30% is exported into the United States. As a small business exporting into the US, we comply with FDA regulations in all respects.

Our concern with the proposed new regulations revolves around the fact that we deal with our US customers from Canada and therefore do not presently have an agent in the United States. I have spoken with three US attorneys who have knowledge of the healthcare business and all have stated that they would be unwilling to act as an agent for a Canadian company. I am sure that a more in-depth search would enable us to find such an agent but I suspect that the cost of appointing a qualified company will be absolutely prohibitive.

While I understand FDA's concern in regards to importation of offshore medical devices without appropriate accountability in the event of an adverse product experience, I believe there are methods of dealing with this issue without penalising small exporters such as Techlem Medical. In view of the close working relationship between the FDA and Health Canada, I see no reason why Canadian authorities could not act on behalf of the FDA to protect the medical community on both sides of the border. In addition, I would think that the North American Free Trade Agreement would preclude US authorities from taking this action when, to my knowledge, there is no Canadian legislation requiring Canadian agents for US establishments.

I appreciate the opportunity to voice my company's concerns on this matter and would be willing to discuss further with you or the appropriate committee.

98N-1215

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Yours Sincerely,

A handwritten signature in black ink, appearing to read "Gill", written over a horizontal line.

Peter Gill
President

c.c. Canadian Embassy
Ontario Exports Inc.

Ms Birgit Mattieson
Ms Debbie Walker

FOOD AND DRUG ADMINISTRATION
OFFICE OF POLICY, PLANNING, AND LEGISLATION

Routing and Transmittal Slip				Date: October 7, 1999	
To:	(Name, office symbol, room number, building, Agency/Post)			Initials	Date
1.	Dockets Management Branch				
2.					
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	Coordination		Justify	

REMARKS:

Please file the attached document in docket number 98N-1215. You may omit this transmittal slip from the docket.

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances and similar actions.

FROM: (Name, org. symbol, Agency/Post) Philip L. Chao	Room No. - Building. <div style="display: flex; justify-content: space-between;"> 15-74 Parklawn </div> Phone Number: 7-3380
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